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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/277,575	03/27/1999	MARTHA KAREN NEWELL	V00139/70028	3748

7590 03/26/2003
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BOSTON, MA 02210

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/26/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/277,575

Applicant(s)

NEWELL, MARTHA KAREN

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14, 18, 29, 39, 44, 47, 49-53, 74, 79, 140 and 143-148 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 14, 18, 29, 47, 49-53, 74, 79 and 140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 7-13, 39, 44 and 143-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,5,6,9 //
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V, claims 1-4, 7-13, 39, 44 and 143-148 in Paper No. 13, filed 1-14-02, is acknowledged. The traversal is on the ground(s) that a search and examination of other agents encompassed by the same claims would not require undue burden. This is not found persuasive because a search of methods comprising each of the recited agents are distinct for the reasons given in the restriction mailed 8-02-01 (Paper No. 12), and as such have acquired a separate status in the art because of their recognized divergent subject matter. MPEP 803 states that: "For the purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation, either separate classification, separate status in the art, or different field of search. Because a search in the non-patent literature of a method comprising each of the recited species would not be co-extensive with a search of a method comprising all of the non-elected recited species in the claims, an examination and search of a method comprising all of the recited species in the claims in a single application would constitute a serious undue burden on the Examiner, and therefore, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species Tumor cell, CD4, B7-2 and UCP expression vector in Paper No. 21, filed 99-30-02, is acknowledged. Because no prior art was found the species requirement was withdrawn.

Claims 5-6, 14, 18, 29, 47, 49-53, 74, 79, and 140 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. Paper No. 13, filed 1-14-02.

Note the claims will be examined only to the extent of the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-4, 7-13, 39, 44 and 143-148 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for decreasing mitochondrial membrane potential in a mammalian cell and for inducing the expression of the immune molecule of MHC Class II HLA-DR, comprising administering an MHC class II ligand, does not reasonably provide enablement for said method wherein said method comprises the additional step of contacting said cell with an amount of an MHC Class II HLA-DR inducing agent effective to induce expression of any immune molecule including MHC class II HLA-DR on the surface of the mammalian cell, wherein said agent is any fatty acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claims are drawn to a method for decreasing mitochondrial membrane potential in a mammalian cell comprising administering an MHC class II ligand, and a method for decreasing mitochondrial membrane potential in a mammalian cell comprising administering an MHC class II ligand wherein said method comprises the additional step of contacting said cell with an amount of of an MHC Class II HLA-DR inducing agent effective to induce expression of MHC class II HLA-DR on the surface of the mammalian cell, wherein said agent is a fatty acid.

The instant specification discloses on page 7 that a fatty acid is a preferred MHC Class II HLA-DR inducing agent which induces expression of MHC Class II on the cell surface. And the specification discloses on page 96 that Figure 22 shows that in an in vitro assay in which the fatty acid oleic acid was used a carbon source, the leukemic tumor cell line L1210 used oleic acid at a much lower rate than the methotrexate resistant derivative leukemic cell line L1210DDP. However the instant specification does not exemplify that oleic acid or any other fatty acid, induces HLA-DR expression. A search of the art at the time the invention was made does not appear to teach that fatty acid induces HLA-DR expression. Therefore, in view of the state of the art at the time the invention was made regarding the ability of a fatty acid to induce HLA-DR expression, and given the insufficient guidance in the specification regarding the ability of a fatty acid to induce the expression of HLA-DR, it would require undue experimentation for one of skill to practice the claimed method which encompasses inducing HLA-DR expression with a fatty acid, without further direction from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 39, 143, 145-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrows et al. Cancer Research 52:2954 Abstract

Burrows et al teach a murine model in which anti-MHC Class II antibody is administered in mice that were administered neuroblastoma transfected with the interferon gamma gene.

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Burrows et al teaches MHC was induced on the tumor vasculature endothelium, B lymphocytes, macrophages and some epithelial cells. The limitation of decreasing the membrane potential of the cell would be an inherent property resulting from the administration of the anti-MHC Class II antibody. Therefore, the referenced teachings anticipate the claimed invention.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640,
March 24, 2003

Amy DeCloux
3-24-03